MAY - 7 2007

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: 070452.

Submitter:	Bio-Rad Laboratories, Inc. Clinical Diagnostics Group 4000 Alfred Nobel Drive, Hercules, California 94547 Phone: (510) 741-5309 FAX: (510) 741-6471
Contact Person:	Jackie Buckley Regulatory Affairs Representative
Date of Summary Preparation:	February 14, 2007
Device Name:	VARIANT™ II Hemoglobin A1c Program (Catalog number 270-2101NU)
Classification Name:	Assay, Glycosylated Hemoglobin, 81LCP
Predicate Device:	VARIANT™ II Hemoglobin A1c Program K984268 Bio-Rad Laboratories, Inc. (Catalog number 270-2101)
Intended Use:	The Bio-Rad VARIANT II Hemoglobin A1c Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high performance liquid chromatography (HPLC). The Bio-Rad VARIANT II Hemoglobin A1c Program is intended for Professional Use Only.
Indications for Use:	Measurement of percent hemoglobin A1c is effective in monitoring long-term glucose control in individuals with diabetes mellitus.

Description of the Device:

The VARIANT II Hemoglobin Testing System uses the principles of high performance liquid chromatography (HPLC). The VARIANT II Hemoglobin A1c Program is based on chromatographic separation of Hemoglobin A1c on a cation exchange cartridge.

Technical Characteristics Compared to the Predicate:

The new VARIANT II Hemoglobin A1c Program (270-2101NU) and the predicate VARIANT II Hemoglobin A1c Program (270-2101) have the same technical characteristics that are summarized in the table below:

Characteristics	VARIANT II Hemoglobin A1c (270-2101NU)	VARIANT II Hemoglobin A1c (270-2101) (k)984268
Analyte Measured: Reported	%Hemoglobin A1c	%Hemoglobin A1c
Intended Use	The Bio-Rad VARIANT II Hemoglobin A_{1c} Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high performance liquid chromatography (HPLC). The Bio-Rad VARIANT II Hemoglobin A1c Program is intended for Professional Use Only.	The Bio-Rad VARIANT II Hemoglobin A_{1c} Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high performance liquid chromatography (HPLC). For In Vitro Diagnostic Use.
Assay Principle	Cation exchange high performance liquid chromatography	Cation exchange high performance liquid chromatography
Sample Type	Human anticoagulated whole blood (EDTA)	Human anticoagulated whole blood (EDTA)
Visible Detection	415 nm	415 nm
Total Area Range	1.5 – 4.5 million µvolt•second	1.0 – 4.0 million µvolt•second
Calibration Frequency	After installation of the analytical cartridge and once every 30 days	After installation of the analytical cartridge
Reconstituted Calibrator Stability	30 days	7 days
Calibrator Reconstitution Volume	7 mL	5 mL
Cartridges Included in Kit	1 Cartridge (1000 tests)	2 Cartridges (500 tests each)
Standardization	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP).	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP).

Testing To Establish Substantial Equivalence:

Accuracy:

Method correlation between the new VARIANT II Hemoglobin A1c Program (270-2101NU) and current VARIANT II Hemoglobin A_{1c} Program (270-2101) was evaluated using 42 EDTA whole blood patient samples ranging from 4.2% to 10.9% HbA_{1c}. The results are presented in the following regression table.

Regression Method	n	R^2	Slope	Intercept
Least Squares	42	0.989	1.056	-0.105

Precision:

The following table provides comparison data on the precision between the new VARIANT II Hemoglobin A1c (270-2101NU) and VARIANT II Hemoglobin A1c (270-2101) Programs, each utilizing low and high EDTA whole blood patient samples, and both tested against samples with moderate (5.4/5.5) and high (8.8- 13.7) % A1c content.

Method precision was performed using a protocol based on the NCCLS Evaluation protocol, Vol.24, No. 25, EP5-A2 (2004) for the new VARIANT II Hemoglobin A1c (270-2101NU) and NCCLS Evaluation protocol, Vol.12, No. 4, EP5-T2 (Mar. 1992) for the current VARIANT II Hemoglobin A_{1c} Program (270-2101). The protocols for both the new VARIANT II Hemoglobin A1c and current VARIANT II Hemoglobin A1c Programs are similar.

For the new VARIANT II Hemoglobin A1c Program protocol, six VARIANT II Hemoglobin Testing Systems at three Bio-Rad sites were utilized. Each site was provided with the same sample set and performed two replicates of each sample on each of 2 runs/day for 10 days.

For the current VARIANT II Hemoglobin A1c Program protocol, 40 runs (2 per day) were performed on one VARIANT II Hemoglobin Testing System over 20 working days. In each duplicate daily run, one aliquot of low HbA1c and one aliquot of high HbA1c patient samples were each analyzed per run.

Although the precision samples are different, since they were run at different time periods, the precision results between the new VARIANT II Hemoglobin A1c (270-2101NU) and the current VARIANT II Hemoglobin A1c Program (270-2101) are equivalent. A summary of combined comparative precision results is presented in the following precision table.

VARIANT II Hemoglobin A1c (270-2101NU) and VARIANT II Hemoglobin A1c (270-2101) Precision

	New VARIANT II Hemoglobin A1c (270-2101NU)		VARIANT II Hemoglobin A1c (270-2101)	
	Low Patient (HbA_{1c})	**High Patient (HbA_{1c})**	**Low Patient (HbA_{1c})**	**High Patient (HbA_{1c})**
n= (number of samples)	240	160	80	80
Mean	5.5	8.8	5.4	13.7
Within run (%CV)	0.9	0.6	1.46	0.65
Within Device Precision (%CV)	1.60	1.38	NA	NA
Total Precision (%CV)	NA	NA	2.14	1.68

Linearity:

	VARIANT II Hemoglobin A1c Program (210-2101NU)	VARIANT II Hemoglobin A1c Program (270-2101)
Linear Range	3.1 – 18.5 % HbA1c	1.3 – 18.9 % HbA1c

Interfering Substances:

Interfering Substance	VARIANT II Hemoglobin A1c (270-2101NU)	VARIANT II Hemoglobin A1c (270-2101)
Bilirubin	No interference up to 20 mg/dL	No interference up to 20 mg/dL
Lipids (Triglycerides)	No interference up to 6000 mg/dL	No interference up to 6000 mg/dL
EDTA	No interference up to 11X EDTA	No interference up to 11X EDTA
Hemoglobin F	10%	15%

Conclusion:

When considering the similarities of the intended use, the general characteristics of the two assays, the use of the same technology and the similar correlation, accuracy and linearity between the two methods, it can be concluded that the new VARIANT II Hemoglobin A1c Program (270-2101NU) is substantially equivalent to the cleared and currently marketed predicate, VARIANT II Hemoglobin A_{1c} Program (270-2101).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Bio-Rad Laboratories, Inc.
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Hercules, CA 94547

MAY - 7 2007

Re: k070452
Trade Name: Variant II Hemoglobin A1c Program
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, KRZ
Dated: February 14, 2007
Received: February 16, 2007

Dear Ms. Buckley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
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Enclosure

Indications for Use

510(k) Number (if known): k070452

Device Name: VARIANT II Hemoglobin A1c Program

Indications For Use:

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The Bio-Rad VARIANT II Hemoglobin A1c Program is intended for Professional Use Only.

Measurement of percent hemoglobin A1c is effective in monitoring long-term glucose control in individuals with diabetes mellitus.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K070452